

Note

Differences in the classifications of biotech products, the connection of producing companies to pharmaceutical research and other institutions, and the small size of the many start-up companies make obtaining precise and comparable statistics difficult. This report employs Ernst & Young's definition of biotechnology and the statistical data, since the firm's reports on the state of biotechnology in Germany are widely accepted as standard.

(According to Ernst & Young *biotechnology* includes *all innovative methods, products and treatments containing living organisms or their cellular parts, as well as, all commercial transfer of knowledge from the fields of molecular biology, virology, and microbiology and cell biology*. Products and treatments that are not purely life science, but that play a significant role in the biotech industry, such as bio-informatics and combinatorial analysis, also fall in this category. The focus is on "core biotech firms" whose aim is the commercialization of modern biotech products, technologies and services.)

Market Overview

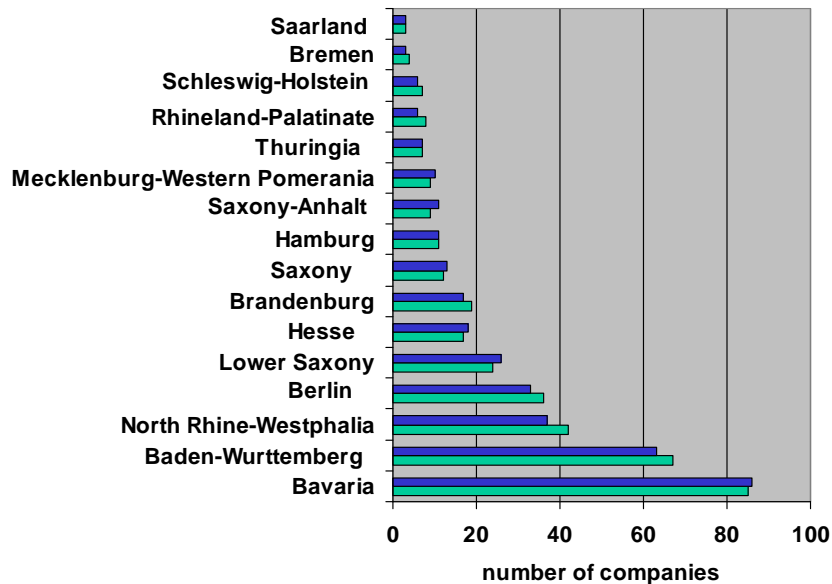
Over the past eight years, Germany became the fastest growing biotechnology market in Europe: 21 % of Europe's biotech companies are located in Germany. Nevertheless, since 2002 the German biotech industry has been facing economic difficulties, similar to other global industries.

Table I: The German Biotechnology Industry

					Total Industry	Public Companies
Year	2001		2002		2003	2003
General Data						
Number of Companies	365	-1%	360	-3%	350	11
Number of Employees	14,408	-7%	13,400	-14%	11,535	3,431
. In R&D	7,858	-7%	7,308	-16%	6,120	1,333
Financial Data (USD million)						
Revenues	1.171	- 8 %	1.075	+3%	1.104	540
R&D Expenditures	1.375	- 16%	1.155	-4%	1.111	162
Net loss	-617	+13%	-701	-10%	-631	-115
Exchange Rate EUR 1 =	USD 1.12		USD 1.06		USD 1.15	

The number of German core biotech firms did not increase for the second year in a row. But originally predicted declines of around 50% did also not occur and are no longer expected to happen in the future. Revenues increased (by 3%) for the first time since 2000 and losses could be reduced, but still amount to US\$ 631 million. However, a promising sign is that 20% of the companies report profits. The regional distribution of the German core biotech companies experienced only minor changes in the last year:

Table II: Core Biotech Companies per Federal State



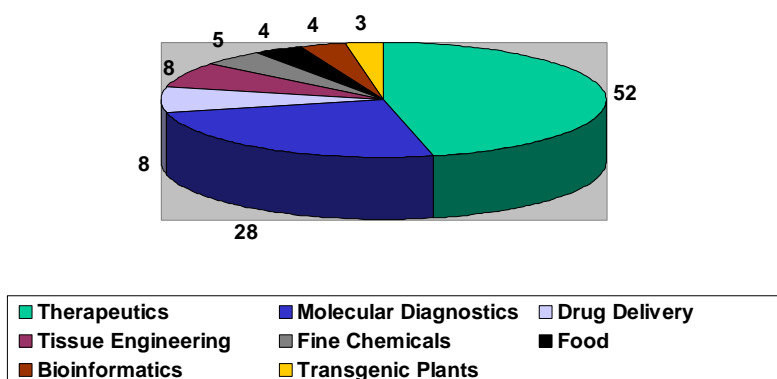
The number of biotech firms in Germany has slightly decreased in 2003, to 350 from 360 in 2002. The number of employees declined by 14% to 11,535, at the same time, revenues rose to US\$ 1.1 million. The first German biotechnology company received marketing approval for one of their products from “BfArM” (the Federal Institut for Pharmaceuticals and Medical Devices): Leuprogel (in the United States marketed under the trade name Eligard) is a drug to treat advanced prostate cancer. This first approval has attracted worldwide attention to the German biotech market and has increased optimism within the industry.

Product Ranges

The industry's main focus is still on the development of therapeutical components, followed by the development of molecular diagnostics. This implies that the vast majority of biotech companies (92%) still focuses on “red” biotechnology (referring to medical applications). “Green” biotechnology with applications in the food and agricultural industry was still underdeveloped in 2003 (13% of the German core biotech companies were active in this field). Also “white”, which covers fine chemicals and “grey” biotechnology, which deals with environmental applications, were relatively small with 13%.

Table III: Number of German Companies Active in the Biotech Sector according to Segments [in%]

(Please note: Total of percentages may exceed 100 as companies are active in more than one area)



Concerning their technologies more than half of the firms employ genomics, screening and assays, as well as cell- and tissue cultures. Proteomics and bioinformatics also play important roles, in addition to molecular modeling and combinatorics. A wide array of promising components generated by German biotech firms is waiting to be marketed in the near future.

Financial Scenario

The main source of capital for German biotech companies are institutional investors (36%), followed by public investors (29%), 21% were financed by private investors and the rest by other sources. Most firms are financed by venture capital; only 5% are listed on the German stock market,

Table IV: Top 10 VC Financings of the German Core Biotech Companies in the year 2003

Company	Invested Capital (million USD)	Lead Investors
Cellzone AG	34.5	INVESCO Private Capital (New York)
Alantos Pharmaceuticals AG	27.7	Oxford Bioscience Partners (Boston)
Epigenomics AG	24.2	MPM Capital (Boston)
Ingenium Pharmaceuticals AG	15.9	HBM Bioventures (Schweiz), TVM (Munich, Boston), Polaris Venture Partners (Boston)
U3 Pharma AG	15.3	Atlas venture(Boston, Amsterdam,Muenchen, London, Paris), LCF Rothschild Venture Partners (Paris)
MTM Laboratories AG	13.8	HBM Bioventures (Schweiz), Wellington Partners (Munich)
4SC AG	10.4	Deutsche Venture Capital (Munich)
Paion GmbH	9.6	NeoMed Management (New York)
Biofrontera Pharmaceuticals AG	8.8	Heidelberg Innovations (Heidelberg)
Antisense Pharma GmbH	7.5	S-Refit (Regensburg)

Government Role

In 2004, "High Tech Masterplan" was introduced by the German government, which provides USD 575 million to strengthen the technology location Germany. This plan intends primarily to facilitate and optimize access to venture capital. Other features of the program are a stronger motivation for start-ups and the encouragement of research. Another program called BioChance PLUS, with a volume of USD 115 million is aimed at supporting small and medium-sized biotech businesses and was introduced in October 2003. With respect to the addition of new European markets and the eastern enlargement, Germany's role as potential "Gateway to the East" should not be underestimated. U.S. firms cooperating with German biotech firms clearly have an advantage when trying to enter the eastern markets.

Technological Cooperations

Throughout 2003, numerous German biotech firms announced the formation of official partnerships. Most of these (44%) were technological cooperations, emphasizing the joint use of one shared technology platform in their research. Another 43% were product cooperations, which aim at the joint development of a product, with an emphasis on completing the total development. The remaining 13% covered marketing agreements. The number of agreements with American firms has also increased, in 2002 about 16% of the deals were concluded with U.S. firms, in 2003 around 20%.

Marketing Cooperations

Especially in the field of marketing cooperations the number of partnerships with U.S. firms has increased remarkably in 2003, accounting for 49% of all marketing agreements (2002: 34%). Marketing agreements of German firms with other domestic companies reached 12%, with other European companies 27%, and with Japanese companies 12%.

Table V: Selected published deals of German Biotech Companies in 2003

	Agreements between German and U.S. companies	
	Private	Public
Biotech – Biotech	<ul style="list-style-type: none">• Apovia (Martinsried) – Corixa (Seattle)• Cenix BioScience (Dresden) – Ambion (Austin, Texas)• Graffinity Pharmaceuticals (Heidelberg)– Genentech (South San Francisco)• Ingenium Pharmaceuticals (Martinsried) – Sequenom (San Diego, CA)• Micromet (Munich) – MedImmune (Gaithersburg, MD)• Morphochem (Munich) – Xenogen (Alameda, CA)	<ul style="list-style-type: none">• Evotec OAI (Hamburg) – Dynogen Pharmaceuticals (Waltham, MA)• Qiagen (Hilden) – Affymetrics (California)• Qiagen (Hilden)- IntradiGM (Rockville, MD)
Biotech – Pharma	<ul style="list-style-type: none">• Epigenomics (Berlin) – Wyeth (Madison, NJ)	<ul style="list-style-type: none">• MorphoSys (Martinsried) – Pfizer (New York, NY)• GPC Biotech (Martinsried) – Eli Lilly (Indianapolis, IN)

<p>Biotech – other industrial partner</p>	<ul style="list-style-type: none"> • Greenovation (Freiburg) – Dow Chemicals • Xantos Biomedicine (Munich) – Ardais (Lexington, MA) 	<ul style="list-style-type: none"> • LION bioscience (Heidelberg) – Delta Soft (Hillsborough, N.J.) • LION bioscience (Heidelberg) – Silicon Genetics (Redwood City, CA) • Qiagen (Hilden) – Thermo Hybaid (Franklin, MA) • Qiagen (Hilden) – Agilent Technologies (Palo Alto, CA)
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Market Access

The acceptance of biotech products in the German market has increased. A study conducted by the VFA (German Association of Research-based Pharmaceutical Companies) dealt with the acceptance of genetically modified medicine. The study found that the number of people who would use genetically modified drugs without any concern has increased from 57% in 1998 to 62% in 2002. The number of people who would never use them has declined.

In the biotech sector, patents play a major role, as intangible assets they have a significant impact on future growth as well as on the financing of a firm. Patent protection in the European Union and the United States is for a period of 20 years after filing. Unlike the United States, which prohibits access to a registration dossier for five years only after market approval, most EU member states currently prohibit commercial research by generic manufacturers for up to ten years following market approval, slowing marketing after the patent expires. Extensions of patent protection for the approval process time are allowed in the EU for up to a maximum time of 15 years following market approval. Scientific research by competitors can only be performed as long as the patent is not breached, and bio-equivalence research with the substance under patent is not permitted. Generic manufacturers from countries such as the United States, where scientific research during the patent protection period is legal five years after market approval, gain an advantage of currently more than 18 months over EU manufacturers.

In 1998, the European Guidelines for the Protection of Biotech Inventions (98/44/EG) were passed by the European Union. These guidelines establish that humans and human body parts, including organs, limbs, bodily fluids, nucleotide sequences and molecules found in the human body in their natural state cannot be patented. Only if the inventor connects a gene to a particular function and finds an industrial application of an isolated gene sequence, the inventor may apply for a patent. Although these guidelines should have been incorporated into national law by July 1, 2000 nearly half of the EU states have not yet adapted these.

**Table VI: Patent Applications for Drugs developed with Biottechnology
(German Patent Office, classification A61K)**

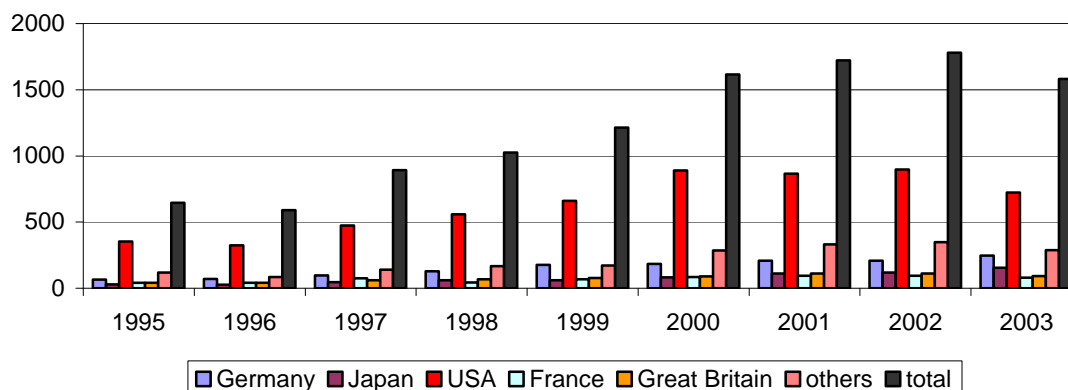


Table VII: Approximate USA share in the total sum of patents

1995	1996	1997	1998	1999	2000	2001	2002	2003
54,5%	55%	53%	54,5%	54%	55%	50%	50%	46%

From 1996 to 2002 the number of patent applications for drugs developed by German life science companies has constantly increased, altogether by 302 %. In 2003, growth stagnated. The United States is the major source to foreign patents used in Germany wit a 50% share of all patents sold.

Conclusion

In spite of a decrease in government subsidies, many German biotech firms have advanced to become global players, which is reflected in the increasing volume of international deals. This opens the market for U.S. companies which seek to out-license their technology or who are looking for a research alliance with a larger German biotech firm. U.S. firms can also still benefit from in-licensing platform technologies developed in German laboratories.

Contact Information

- Associations and Economic Developers

European Private Equity & Venture Capital Association

Minervastraat 4

B – 1930 Zaventem (Brussels)

Tel: + 32 2 715 00 20

Fax: + 32 2 725 07 04

Internet: <http://www.evca.com/html/home.asp>

Email: evca@evca.com

BVK: Bundesverband deutscher Kapitalgesellschaften

Reinhardtstrasse 17c
Residenz am Deutschen Theater
10117 Berlin
Tel: +49-30-30 6982-0
Fax: +49-30-30 6982-20
Internet: <http://www.bvk-ev.de/>
Email: bvk@bvk-ev.de

InformationsSekretariat Biotechnologie

Theodor-Heuss-Allee 25
60486 Frankfurt am Main
Tel: +49-69 7564 160
Fax: +49-69 7564 169
Internet: <http://www.dechema.de/>
Email: isb@dechema.de

Deutsche Industrie Vereinigung Biotechnologie

Karlstr. 21
60329 Frankfurt am Main
Tel: +49-69 2556-0
Fax: +49-69-2556-1471
Internet: <http://www.vci.de/>
Email: internetinfo@vci.de

- Trade shows, Conferences, Partnering Events

BioAnalytica 2004

Second International Trade Fair and BioAnalytica Conference
Europe's BioIndustry and Suppliers Business Platform
5. - 7. April 2005
Neue Messe Muenchen
Messe Muenchen GmbH
Messegelaende
81823 Muenchen
Tel. (+49 89) 949 – 11 488
Fax (+49 89) 949 – 11 489
Email: info@bioanalytica.de
Internet: www.analytica-world.com

Biotechnica 2005

International Trade Fair for Biotechnology
18. – 20. October 2005
Deutsche Messe AG
Messegelaende
D-30521 Hannover
Internet: www.biotechnica.de

Drug Discovery Technology

9th Annual Conference
14.- 16. March 2005
Novotel London West
London
United Kingdom

Internet: www.drugdisc.com

7th Annual C21 BioVentures

The Future of BioVenture Investing
Biotechnology, Informatics, Medical Devices and Health Care Services
22 – 23 March 2005
London
Great Britain
Internet: www.techvision.com

- Commercial Service Contact

U.S Commercial Service
U.S. Consulate General
Mr. Sebastian Koehler
Sr. Commercial Specialist
Alsterufer 27
20354 Hamburg
Tel: [49] [40] 41171 223
Fax: [49] [40] 41065 98
Email: sebastian.koehler@mail.doc.gov
Internet www.buyusa.com